

Package leaflet: Information for the patient

Furosemide 20mg Spironolactone 50mg

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

What is in this leaflet:

- 1. What Spiromide Capsules are and what they are used for**
- 2. What you need to know before you take Spiromide Capsules**
- 3. How to take Spiromide Capsules**
- 4. Possible side effects**
- 5. How to store Spiromide Capsules**
- 6. Contents of the pack and other information**

1. What Spiromide Capsules are and what they are used for

The name of your medicine is Lasilacton 20mg/50mg Capsules (called Spiromide Capsules throughout this leaflet). Spiromide Capsules contain two different medicines called: furosemide and spironolactone. Both belong to a group of medicines called diuretics (water tablets). Spiromide Capsules can be used to stop the build up of extra water in your body. This extra water can cause swollen ankles, shortness of breath and feeling more tired than usual. Spiromide Capsules work by helping you to pass more water (urine) than you usually do. If the extra water in your body is not removed, it can put extra strain on the heart, blood vessels, lungs, kidneys or liver.

2. What you need to know before you take Spiromide Capsules

Do not take Spiromide Capsules and tell your doctor if:

You are allergic (hypersensitive) to furosemide, spironolactone or any of the other ingredients of Spiromide Capsules (listed in Section 6 below) Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue

- You are allergic to sulphonamides such as sulfadiazine or co-trimoxazole
- You have severe problems with your kidneys
- You have severe liver problems
- Your doctor has told you that you have a low blood volume or are dehydrated
- You are not passing any water (urine)
- You have too much or too little potassium or sodium in your blood (shown in blood tests)
- You have an illness called 'Addison's Disease'. This can make you feel tired and weak

- You are breast-feeding (see "Pregnancy and breast-feeding" section below) Do not take Spiromide Capsules if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Spiromide Capsules.

Warnings and precautions

Talk to your doctor or pharmacist before taking Spiromide Capsules if:

- You have difficulty in passing water (urine)
- You are 65 years of age or older
- You have liver problems or kidney problems
- You have diabetes
- You are taking other medicines which change the amount of potassium in your blood (see "Taking other medicines" section below)
- You are an elderly patient with dementia and are also taking risperidone
- You have low blood pressure or feel dizzy when you stand up
- You have prostate problems
- You have gout
- You feel dizzy or dehydrated.
- This can happen if you have lost a lot of water through being sick, having diarrhoea or passing water very often. It can also happen if you are having trouble drinking or eating
- You are going to have a glucose test
- You are taking any other water tablets
- You rely on your voice to make a living. Spiromide Capsules can cause changes to your voice
- You have systemic lupus erythematosus
- You are elderly, or you are on other medications which can cause the drop of the blood pressure and you have other medical conditions that are risks for the drop of blood pressure.
- Concomitant administration of Spiromide Capsules with certain medicines, potassium supplements and food rich in potassium may lead to severe hyperkalaemia (increased potassium blood level).
- The symptoms of severe hyperkalaemia might include muscle cramps, irregular heart rhythm, diarrhoea, nausea, dizziness or headache.
- If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Spiromide Capsules

Other medicines and Spiromide Capsules

Tell your doctor or pharmacist if you are taking, haven't recently taken or might take any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Spiromide Capsules can affect the way some other medicines work. Also, some medicines can affect the way Spiromide Capsules work

In particular, tell your doctor if you are taking any of the following:

The following medicines can affect the way Spiromide Capsules work and increase the chance of you getting side effects:

- Medicines which change the amount of potassium in your blood. These include potassium supplements such as potassium chloride or certain water tablets (diuretics) such as triamterene and amiloride
- Medicines such as ramipril, enalapril, perindopril (called 'ACE inhibitors') or losartan, candesartan, irbesartan (called 'angiotensin II receptor antagonists'). Your doctor may need to change the dose of your capsules or ask you to stop taking them
- Medicines for high blood pressure or heart problems. Your doctor may need to change the dose of your medicine
- Medicines used as a general anaesthetic for relaxing your muscles during surgery
- Medicines for diabetes. These may not work as well when you are taking Spiromide Capsules
- Theophylline - used for wheezing or difficulty in breathing
- Phenytoin - used for epilepsy. This can lower the effect of Spiromide Capsules
- Trimethoprim and trimethoprim-sulfamethoxazole

The following medicines can increase the chance of side effects when taken with Spiromide Capsules:

- Lithium - used for mental illnesses. To help stop side effects your doctor may need to change the dose of your lithium and check the amount of lithium in your blood
- Cisplatin - used for some cancers
- Digoxin - used for heart problems. Your doctor may need to change the dose of your medicine
- Non-steroidal anti-inflammatory drugs (NSAIDs) - used for pain and inflammation such as aspirin, ibuprofen, ketoprofen or indometacin
- Carbamazepine - used for epilepsy
- Aminoglutethimide - used for breast cancer
- Ciclosporin - used to stop the rejection of organs after a transplant
- Methotrexate - used for cancers of the skin, joint or bowel diseases
- Carbenoxolone - used for ulcers of the food-pipe (gullet)
- Reboxetine - used for depression; if used for a long time
- Amphotericin - used for fungal infections; if used for a long time
- Corticosteroids used for inflammation such as prednisolone
- Liquorice used in cough preparations; if taken in large amounts
- Probenecid (used with another HIV medicine)
- Colestyramine - used for lowering cholesterol
- Medicines for infection such as gentamicin, amikacin, neomycin, netilmicin, tobramycin, vancomycin or high doses of cephalosporins

- Medicines used as injections before X-ray examinations
- Medicines used for constipation (laxatives) such as bisacodyl or senna; if used for a long time
- Medicines for asthma when given in high doses (such as salbutamol, terbutaline sulphate, salmeterol, formoterol or bambuterol)
- Other water tablets (diuretics) such as bendroflumethiazide.
- Your doctor may need to change the dose of your medicine.

Spiromide Capsules with food and drink

Spiromide Capsules should be swallowed with a full glass of water and preferably with food.

Pregnancy and breast-feeding

Do not take Spiromide Capsules if you are pregnant. Talk to your doctor before taking this medicine if you are pregnant, might become pregnant, or think you might be pregnant. Do not breast-feed if you are taking Spiromide Capsules. This is because small amounts may pass into the mother's milk. Talk to your doctor before taking this medicine if you are breast-feeding or planning to breast-feed. Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines

You may feel dizzy or unwell after taking Spiromide Capsules. If this happens, do not drive or use any tools or machines.

Spiromide Capsules contain lactose

If you have been told by your doctor that you cannot tolerate some sugars, talk to your doctor before taking this medicine.

How to take Spiromide Capsules

Always take Spiromide Capsules exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

Take this medicine by mouth

Swallow the capsules whole with a drink of water

This medicine is not suitable for use in children

If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor

How much Spiromide Capsules to take

The usual dose is one to four capsules daily. Your doctor will tell you how many capsules to take. If you have to take your capsules once each day, take with your breakfast. If you have to take your capsules twice each day, take with your breakfast and lunch. Do not take your capsules in the evening, as it could affect your sleep.

If you are taking sucralfate (a medicine for stomach ulcers)

Do not take sucralfate at the same time as Spiromide Capsules. Take your dose at least 2 hours before or after Spiromide Capsules. This is because it can affect the way your medicine works.

If you take more Spiromide Capsule- than you should

If you think you may have taken more Spiromide Capsules than you should, or if a child has swallowed any of your capsules, tell your doctor or go to your nearest hospital casualty department straight away. Remember to take with you any medicine that is left so the doctor knows what you have taken. The following effects may happen: dry mouth, feeling thirsty, muscle pain or cramps, feeling sick or being sick (vomiting), weak or uneven heartbeat, feeling dizzy, weak or sleepy.

If you forget to take Spiromide Capsules

If you forget a dose, take it as soon as you remember it. Then continue the following morning as normal. Do not take a double dose to make up for a forgotten dose.

If you stop taking Spiromide Capsules

Keep taking Spiromide Capsules until your doctor tells you to stop taking it.

Blood tests

Your doctor may carry out blood tests to check that the levels of some salts in the blood are at the correct levels. If you have any further questions on the use of this product, ask your doctor or pharmacist.

Possible side effects

Like all medicines, Spiromide Capsules can cause side effects, although not everybody gets them. Tell a doctor straight away if you notice any of the following serious side effects - you may need urgent medical treatment

Frequency not known (Cannot be estimated from the available data)

- If you have an allergic reaction. The signs may include inflammation of the kidney (nephritis) or kidney failure, swollen ankles or high blood pressure, skin rashes, change in skin colour, severe blistering of the skin, being more sensitive to the sun than usual, high temperature (fever), and itching

- Severe allergic reactions. The signs may include shock such as difficulty in breathing, cold clammy skin, pale skin colour and racing heart beat
- Severe stomach or back pain. These could be signs of 'pancreatitis'
- Bruising more easily, getting more infections, feeling weak or tired more than usual. Spiromide Capsules can affect the number of blood cells, causing serious blood problems.
- Increased thirst, headache, feeling dizzy or light-headed, fainting, confusion, muscle or joint pains or weakness, cramps or spasms, stomach upsets or uneven heartbeats. These could be signs of dehydration or changes in your normal body chemicals. Severe dehydration can lead to blood clots or 'gout'
- You notice yellowing of your skin or eyes and your urine becomes darker in colour. These could be signs of a liver problem such as jaundice or hepatitis. In patients who already have liver problems, a more serious liver problem known as liver encephalopathy may occur. Symptoms include forgetfulness, fits, mood changes and coma.

Blistering or peeling of the skin around the lips, eyes, mouth, nose and genitals, flu-like symptoms and fever. This could be a condition called Stevens-Johnson syndrome. In a more severe form of the condition called Toxic Epidermal Necrolysis, layers of the skin may peel off to leave large areas of raw exposed skin all over the body.

Acute generalised exanthematous pustulosis (AGEP) (acute febrile drug eruption), symptoms include the skin becoming red with swollen areas covered in numerous small pustules

Dizziness, fainting and loss of consciousness

Tell your doctor as soon as possible if you have any of the following side effects:

Uncommon (may affect up to 1 in 100 people)

- Deafness (sometimes irreversible) Frequency not known (cannot be estimated from the available data) •
- Problems hearing or ringing in the ears (tinnitus). This especially affects people who already have problems with their kidneys
- Tingling or feeling numb on the skin
- Small changes in your mood such as feeling agitated or anxious
- Headaches, feeling dizzy or light-headed when standing up quickly. Also loss of concentration, slower reactions, feeling sleepy or weak, problems with your sight, dry mouth. This could be due to low blood pressure
- Pain before or after eating, black or tar-like stools. This could be a sign of an ulcer in your stomach or gut

Tell your doctor or pharmacist if any of the following side effects get serious or last longer than a few days, or if you notice any side effects not listed in this leaflet

Frequency not known (cannot be estimated from the available data)

- Feeling sick (nausea) or a general feeling of being unwell, diarrhoea and being sick (vomiting) and constipation
- Feeling confused, moving unsteadily or staggering (ataxia)
- Lack of energy
- Feeling drowsy or sleepy (somnolence)
- Headache
- Breast swelling or growth sometimes with nipple pain or sensitivity
- Enlargement of breasts in men. This may go away after you stop taking these capsules.
- Difficulty in getting or maintaining an erection, or in ejaculation
- Redness of the skin
- Hair grows more than normal on the body or face
- Menstrual periods which are heavier or last longer than usual
- Lack/absence of menstrual periods (amenorrhoea)
- Voice changes. For example hoarseness or deepening of the voice in women and changes in the pitch in men. This may remain even after you stop taking these capsules.
- People with bladder and prostate problems may notice pain when passing water. This is due to an increase in the amount of water passed
- If you have diabetes you may be less able to control the levels of glucose in your blood
- Passing more water (urine) than you usually do. This normally happens 1 or 2 hours after taking this medicine
- Symptoms vary considerably between patients but the most common are: joint aches and pains, swollen joints, headaches, increased sensitivity to sunlight, skin rashes, kidney problems, fatigue and weakness, mouth ulcers, hair loss, anxiety and depression, fevers and night sweats abdominal pain, chest pain, shortness of breath, anaemia (systemic lupus erythematosus)

Blood tests

Spiromide Capsules can change the levels of liver enzymes or body fats known as cholesterol and triglycerides.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse.

This includes any possible side effects not listed in this leaflet. You can also report side effects directly via e-mail: PV@searlecompany.com

By reporting side effects you can help provide more information on the safety of this medicine.

How to store Spiromide Capsules

- Keep this medicine out of the sight and reach of children
- Each capsule contains the active substances furosemide 20mg and spironolactone 50mg

By regulatory

For Full prescribing Information, please refer to the SmPC

PIL Code:092017

Rev Code:000000

